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Robert L. McDowell  
1170 Jackson Heights Drive  
Webster, NY 14580

EXAMINER

THOMPSON, MICHAEL M

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/045,688

Applicant(s)

LARSON ET AL. *YCC*

Examiner

Michael M. Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what elasticity in an amount greater than 200% is meant to encompass. Therefore, it is the Examiner's position that any of the broad compositions that Applicant discloses in claim 1 are suitable to fulfill the elasticity requirement of instant claim 12.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1, 5-6, 8, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al.. Sahatjian et al. teaches an implantable drug-deliverable device with a hydrogel coating or film, consisting of a polymer matrix containing a drug. He teaches the "converting" of the polymer containing the drug by cross-linking, the polymer containing polyethylene glycol, and/or polyethylene oxide. Please note that claims directed to exposure of light, specifically

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ultraviolet light are inherent since it is the Examiners position that cross-linking clearly and inherently includes photocrosslinking.

***Claim Rejections - 35 U.S.C. § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-4, 9-12, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian et al. in view of Desai et al. ('640). Sahatjian et al. teaches all of the limitations of the claims except for the polymer comprising sodium alginate, cross-linking effected by calcium chloride, and mannuronic and guluronic acid in the amounts by weight, a polymer comprising both polyethylene oxide, polyethylene glycol in combination with alginate. Desai et al teaches crosslinking of various polymer compositions including several ingredients such as sodium alginate, cross-linking effected by calcium chloride, and mannuronic and guluronic acid in different amounts by weight, and polymers comprising both polyethylene oxide, polyethylene glycol in combination with alginate in various combinations. Therefore, it is the Examiner's position that it would have been obvious to one of ordinary skill in the art, at the time of invention, to have utilized the cross-linked polymer compositions taught by Desai et al. with the implantable device taught by Sahatjian et al. as merely a substitute polymer hydrogel or liquid composition containing at least one therapeutic agent for delivery to a patient and/or for lessening friction of the device. Please note that not only does Desai et al clearly teach that his

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device provides a process for encapsulating a biologic, but the use of polymer matrixes as coatings on implantable medical devices are well known in the art for the same reasons as Applicant. Also note that it is the Examiner's position that arguments supra render obvious as a matter of design choice, the various amounts by weight and percentages of compounds since Applicant lends no specific criticality as to the importance of these ranges and percentage. Furthermore, it is the Examiner's position that at least one of these disclosed drugs is water-soluble and at least one is non-water soluble.

7. Claims 7, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian et al. in view of Loomis. Sahatjian et al. teaches all of the limitations of the claims except for a medical devices including a coated stent and at least one of a pacemaker, vascular graft, suture ring, implantable infusion port, implantable drug delivery pump, orthopedic hardware and appliances, and neurological stimulating devices. Loomis teaches a orthopedic hardware or appliance wherein the cross-linked composition is coating an implantable prostheses. It would have been obvious to one of ordinary skill in the art at the time of invention to have coated any medical device with a cross-linked composition as a delivery vehicle for therapeutic agents with the therapeutic agent within the composition, especially with respect to a orthopedic device as taught by Loomis. Please note that several references are well known in the art to contain various medical devices including stents having coatings with cross-linked composition as a delivery vehicle for therapeutic agents.

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### Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, AnhTuan Nguyen, can be reached on (703) 308-2154. The official fax phone number for submissions to the organization where this application or proceeding is assigned is (703) 872-9302. The official fax phone number for submission of After Final response is (703) 872-9303.

Michael M. Thompson

Patent Examiner

MT 

December 11, 2002

  
ANH TUAN T. NGUYEN  
PRIMARY EXAMINER

12/16/02